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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,286	03/12/2004	Rajagopal Bakthavatchalam	02-090-Z (NEU-02-090-Z)	8664
23520	7590	05/01/2006	EXAMINER	
MAURICE M KLEE 1951 BURR STREET FAIRFIELD, CT 06824			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/799,286	Applicant(s) BAKTHAVATCHALAM ET AL.	
	Examiner Kevin E. Weddington	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 186, 187, 199-208 and 217-222 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 186, 187, 199-208 and 217-222 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-16-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 186, 187, 199-208 and 217-222 are presented for examination.

Applicants' response filed January 24, 2006; and information disclosure statement filed March 16, 2006 have been received.

Accordingly, the rejection made under 35 USC 102(b) and 35 USC 103 as set forth in the previous Office action dated October 19, 2005 at pages 2-5 are hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 201-207 and 217-222 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 77-82 of copending Application No. 10/891,832. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present

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application teaches a method of treating pain in a mammal, the method comprising administering to the mammal a therapeutic dose of a capsaicin receptor antagonist that is not a capsaicin analogue, and the copending application teaches a method for treating pain with the administering of a therapeutically effective amount of a capsaicin receptor broadly. Clearly, the claims of the copending application encompass the claims of the present application since the capsaicin receptors include capsaicin receptor antagonists.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 201-207 and 217-222 are not allowed.

Claims 201-207 and 217-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49-56 of U.S. Patent No. 10/539,031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating pain in a mammal, the method comprising administering to the mammal a therapeutic dose of a capsaicin receptor antagonist that is not a capsaicin analogue, and the copending application teaches a method for treating pain with the administering of a therapeutically effective amount of a capsaicin receptor broadly. Clearly, the claims of the copending application encompass the claims of the present application since the capsaicin receptors include capsaicin receptor antagonists.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 201-207 and 217-222 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 186, 187, 199-208 and 217-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain with a capsaicin receptor antagonist derived from diaryl piperazine compounds disclosed in claims 187 and 208, does not reasonably provide enablement for other capsaicin receptor antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating pain in a mammal, the method comprising administering to the mammal a therapeutic dose of a capsaicin receptor antagonist that is not a capsaicin analogue.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the other capsaicin receptor antagonists beside the ones disclosed in claims 187 and 208

The breadth of the claims

The claims are very broad and inclusive to all capsaicin receptor antagonists other than capsaicin analogues.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of diaryl piperazine compounds of the formula disclosed in claims 187 and 208.

No working examples showing other capsaicin receptor antagonists other than capsaicin analogues were effective in treating pain.

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The quantity of experimentation necessary


Applicants have failed to provide guidance as to how the other capsaicin receptor antagonists are effective in treating pain. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 186, 187, 199-208 and 217-222 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington

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April 26, 2006